EXHIBIT J

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel.,
MIKE HUNTER,
ATTORNEY GENERAL OF OKLAHOMA,

Plaintiff,

vs.

(1) PURDUE PHARMA L.P.;
(2) PURDUE PHARMA, INC.;
(3) THE PURDUE FREDERICK COMPANY;
(4) TEVA PHARMACEUTICALS USA, INC.;
(5) CEPHALON, INC.;
(6) JOHNSON & JOHNSON;
(7) JANSSEN PHARMACEUTICALS, INC.;
(8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.;
(10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.;
(11) WATSON LABORATORIES, INC.;
(12) ACTAVIS LLC; and
(13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC.,

Defendants.

Case No. CJ-2017-816
The Honorable Thad Balkman

Discovery Motion Submitted to:
Special Discovery Master
William C. Hetherington

CONFIDENTIAL
FILED UNDER SEAL
PURSUANT TO
PROTECTIVE ORDER
DATED APRIL 16, 2018

THE STATE'S OMNIBUS RESPONSE TO DEFENDANTS' MOTIONS TO EXCLUDE THE TESTIMONY OF ANDREW KOLODNY, DANIEL CLAUW, ERIN KREBS, AND WILLIAM MCCALLISTER

IN THE DISTRICT COURT OF CLEVELAND COUNTY
STATE OF OKLAHOMA

STATE OF OKLAHOMA, ex rel., MIKE HUNTER, ATTORNEY GENERAL OF OKLAHOMA, Plaintiff, vs. (1) PURDUE PHARMA L.P.; (2) PURDUE PHARMA, INC.; (3) THE PURDUE FREDERICK COMPANY; (4) TEVA PHARMACEUTICALS USA, INC.; (5) CEPHALON, INC.; (6) JOHNSON & JOHNSON; (7) JANSSEN PHARMACEUTICALS, INC.; (8) ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (9) JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC.; (10) ALLERGAN, PLC, f/k/a ACTAVIS PLC, f/k/a ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; (11) WATSON LABORATORIES, INC.; (12) ACTAVIS LLC; and (13) ACTAVIS PHARMA, INC., f/k/a WATSON PHARMA, INC., Defendants.	§ §	Case No. CJ-2017-816 The Honorable Thad Balkman ***Discovery Motion Submitted to***: Special Discovery Master William C. Hetherington **CONFIDENTIAL** **FILED UNDER SEAL** **PURSUANT TO** **PROTECTIVE ORDER** **DATED APRIL 16, 2018**

THE STATE'S OMNIBUS RESPONSE TO DEFENDANTS' MOTIONS TO EXCLUDE THE TESTIMONY OF ANDREW KOLODNY, DANIEL CLAUW, ERIN KREBS, AND WILLIAM MCCALLISTER

Johnson & Johnson moves to exclude select testimony of three of the State's experts: Drs. Kolodny, Clauw, and Krebs,[1] and Teva moves to exclude the testimony of Dr. McCallister (collectively, the "Motions"). The State responds to the Motions in this combined Response.

Defendants' Motions ask the Court to rule, *pre-bench trial*, that these experts cannot testify regarding relevant facts and opinions squarely within the subject matter on which they are nationally-recognized experts. To be clear, Defendants' Motions would fail in any case, as the experts at issue plainly satisfy the Oklahoma Rules of Evidence. However, Defendants' arguments are even more misguided in the context of a bench trial where: (1) concerns regarding unreliable expert testimony reaching a jury do not arise; and (2) Defendants admit the Court can properly decide whether the evidence satisfies § 2702 during the course of trial. Defendants fail to cite any Oklahoma case—state or federal—in support of their Motions arising in the context of a bench trial. Indeed, Defendants fail entirely to acknowledge the relaxed gate-keeping function of the Court in a bench trial.

Further, in a great twist of irony, Defendants' corporate representatives testified that it was appropriate for English majors with no science degree and a couple months of training to "educate" physicians about how to properly prescribe opioids. Exhibit 1, at 705:1-707:12 (Eshleman Depo., Feb. 6, 2019). Yet, remarkably, Defendants now argue that doctors who have dedicated their professional lives to studying the opioid crisis are not qualified to educate the Court regarding its causes and effects. In doing so, they ask this Court to make determinations regarding credibility and weight that are properly reserved for trial, and especially so in a bench trial. They conflate opinions with the facts underlying those opinions and then improperly seek to exclude both. And,

[1] As indicated in the State's witness list served on April 19, the State no longer intends to call Dr. Krebs at trial. J&J's Motion in regard to Dr. Krebs is therefore moot.

Defendants repeatedly argue that experts' personal experiences and observations should be discounted in direct contradiction to both 12 O.S. § 2702 and § 2703. Put simply, Defendants' Motions contort the Oklahoma Evidence Code regarding expert testimony in an attempt to exclude evidence Defendants do not like.

As set forth below, the Court need not address Defendants' arguments now. But, if the Court chooses to do so, it should deny Defendants' Motions.

ARGUMENT AND AUTHORITIES

A. *Daubert* Rulings Are Premature Because This Is a Bench Trial.

While Defendants' Motions must fail on the merits, the Court need not get there. *Daubert* is simply a refinement of the "gatekeeping capacity" of a trial judge recognized in the Oklahoma Evidence Code—a role that specifically relates to the jury. *Christian v. Gray*, 2003 OK 10, ¶ 9, 65 P.3d 591, 599. "[T]he 'gate-keeping' function is less important [during a bench trial] because 'the usual concerns regarding unreliable expert testimony reaching a jury obviously do not arise when a district court is conducting a bench trial.'" *Valley View Dev., Inc. v. United States ex rel. United States Army Corps of Eng'rs*, 721 F. Supp. 2d 1024, 1047 (N.D. Okla. 2010) (citation omitted). Defendants themselves have previously confirmed this is appropriate. According to the J&J Defendants: "the Court has 'substantial flexibility in admitting proffered expert testimony at the front end, and then deciding . . . during the course of trial whether the evidence meets the requirements of . . . *Daubert*.'" J&J's Resp. to Court Order on Jury-Trial Requirements, Briefing Schedule, and Severance, Apr. 9, 2019, at 4 (citing *Valley View*, 721 F. Supp. 2d at 1047).

Here, the Court should exercise its substantial discretion and reserve ruling on the expert testimony at issue until trial. "'[A] court is almost always better situated during the actual trial to assess the value and utility of evidence. Consequently, a court should reserve its rulings for those

instances when the evidence plainly is "inadmissible on all potential grounds" . . . and it should typically defer rulings on relevancy and unfair prejudice objections until trial when the factual context is developed[.]'" *Carroll v. United States*, No. CIV-15-674-D, 2017 U.S. Dist. LEXIS 6076, at *3 (W.D. Okla. Jan. 17, 2017) (citation omitted). While the expert testimony at issue is decidedly admissible, the Court need not make that decision now—the proper course of action is to admit the expert testimony on the front end and decide whether it satisfies *Daubert* in the context of trial.

If the Court does elect to rule on Defendants' Motions now, the challenged testimony should not be excluded. Regardless of when the Court makes *Daubert* determinations, its gate-keeping function is relaxed in the context of a bench trial. And, as set forth below, Drs. Kolodny, Clauw, and McCallister are qualified experts and their testimony is directly relevant to the State's claims, is the product of reliable methods, and will be helpful to the trier of fact.

B. The Legal Standard Governing Expert Opinions.

A determination of whether expert opinion testimony may be introduced is governed by 12 O.S. § 2702, modeled after Federal Rule of Evidence 702, and provides an expert can testify "in the form of opinion or otherwise" if the expert's testimony is based upon sufficient facts or data, utilizes a reliable methodology, and applies the methodology in a reliable manner. *See Christian v. Gray*, 2003 OK 10, 65 P.3d 591, 597-98 (providing 12 O.S. § 2702-2705 are either identical or identical in substance to their federal counterparts).

Relevance turns on whether the expert's reasoning or methodology can be applied to the facts at issue, which is closely related to whether the testimony will be of assistance to the trier of fact. *Id.*, ¶ 9. Reliability concerns whether the expert's testimony has a reliable basis in the knowledge and experience of his discipline. *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1234 (10th

Cir. 2004).[2] Courts have cautioned against applying the reliability requirement too strictly, explaining that "the reliability requirement must not be used as a tool by which the court excludes all questionably reliable evidence." *Alnahhas v. Robert Bosch Tool Corp.*, No. CIV-13-178-D, 2018 U.S. Dist. LEXIS 84853, at *15 (W.D. Okla. May 18, 2018).

The factors helpful in performing the Court's gatekeeping function will vary case-by-case, depending on the type of expert testimony proffered, and the Court has wide discretion in deciding how to assess the reliability and relevance of an expert's opinion. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999); *Carnahan v. Chesapeake Operating, Inc.*, 2015 OK CIV APP 22, 347 P.3d 753, 759 ("[T]he law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination.") (citation omitted, emphasis in original).

C. The Challenged Experts Are Qualified To Provide The Proffered Expert Testimony.

Defendants wrongly argue that Doctors Kolodny and Clauw are not qualified to opine on the effect of pharmaceutical marketing on the opioid crisis because they do not have training in marketing.[3] A witness can qualify as an expert based on "knowledge, skill, experience, training, ***or*** education." 12 O.S. § 2702 (emphasis added). As indicated by the disjunctive "or" in Rule § 2702, any one of the five bases listed in the Rule may be sufficient. *Id.*; Fed. R. Evid. 702 advisory committee's note to 2000 amendment (A witness may be qualified as an expert on the basis of experience alone.). Indeed, a court abuses its discretion if it refuses to qualify a witness as an expert solely because the expert does not have the technical training that the court considers to be

[2] Federal court decisions may be examined for persuasive value when they construe federal evidence rules with language substantially similar to that in Oklahoma statutes. *Willoughby v. Oklahoma City*, 1985 OK 64, 706 P.2d 883, 887.

[3] Defendants do not challenge the qualifications of Dr. McCallister.

most appropriate. *Williams Natural Gas Co. v. Perkins*, 1997 OK 72, ¶¶ 20–21, 952 P.2d 483, 490. Each of the challenged Doctors is a nationally-recognized expert on the opioid crisis. Each has devoted decades to studying the causes and effect of the opioid crisis—including reviewing relevant literature, studies, and Defendants' own marketing materials. And each, as a physician in the very fields targeted by Defendants' marketing, has personally experienced the marketing practices on which he or she will opine and seen the effects of that marketing at the ground level. Accordingly, the State's experts are, at a minimum, qualified to opine on Defendants' opioid marketing based on their knowledge and experience.

1. Dr. Andrew Kolodny

a. Dr. Andrew Kolodny is the Nation's Leading Expert on the Opioid Epidemic

Dr. Andrew Kolodny has dedicated much of his career to studying, researching, writing and teaching about drug manufacturers' role in fueling the oversupply and over-prescription of opioids in this country. Exhibit 2, at 38:7-12; 84:14-17; 85:4-24 (Kolodny Depo., Mar. 27, 2019); *See also* Exhibit 3 (Expert Disclosure of Doctor Andrew Kolodny). Indeed, Dr. Kolodny is widely considered by many—including the Teva defendants—to be a national expert on the opioid epidemic.

Andrew Kolodny, MD
Chair, Psychiatry Department, Maimonides Medical Center
Founder, President, Physicians for Responsible Opioid Prescribing
Dr. Andrew Kolodny is the chair of Psychiatry at Maimonides Medical Center in Brooklyn, NY. Board certified in Psychiatry and Addiction Medicine, Dr. Kolodny is a national expert on the opioid addiction epidemic. In his clinical practice, he specializes in the treatment of opioid addiction. Previously, as Medical Director for Special Projects in the Office of the Executive Deputy Commissioner for the New York City Department of Health and Mental Hygiene, he helped develop and implement city-wide buprenorphine programs, naloxone overdose prevention programs and emergency room-based screening, brief intervention and referral to treatment (SBIRT) programs for drug and alcohol misuse.

Confidential **TEVA-OK-00101720**

Exhibit 4 (TEVA-OK-00101720 - excerpt).

In fact, due to Dr. Kolodny's extensive expertise on the opioid crisis, he has served as a consultant, advisor, and/or expert witness—on the topic of deceptive marketing campaign by opioid manufacturers—to the United States Senate Finance Committee, the United States Senate Homeland Security and Governmental Affairs, the United States Senate Committee on Energy & Commerce, the United States Senate Caucus on International Narcotics Control, the National Governors Association, the National Association of Attorney Generals, National Judicial Opioid Task Force, and many others. Not only is Dr. Kolodny qualified to testify about Defendants' role in creating the opioid crisis, he very well may be the most qualified person in the entire country to testify on the subject.

Currently, Dr. Kolodny is the executive director of Physicians for Responsible Opioid Prescribing (PROP), an organization with a mission to reduce morbidity and mortality caused by overprescribing of opioid analgesics. He is also co-director of the Opioid Policy Research Collaborative at the Heller School for Social Policy and Management at Brandeis University. Dr. Kolodny's additional qualifications include but are not limited to:

- Dr. Kolodny's 2015 review article on the opioid crisis,[4] which details the role of opioid marketing, has been cited by 494 academic publications (as of 4/18/2017), including the United States Surgeon General's Report on Alcohol, Drugs and Health.[5]

[4] Kolodny, A., Courtwright, D. T., Hwang, C.S., Kreiner, P., Eadie, J.L., Clark, T. W., & Alexander, G. C. (2015). The prescription opioid and heroin crisis: A public health approach to an epidemic of addition. *Annual Review of Public Health, 36, 559-574.*

[5] U.S. Department of Health and Human Services (HHS), Office of the Surgeon General, Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: HHS, November 2016.

- Dr. Kolodny's research on conflicts of interest and opioid prescribing guidelines[6] was cited by The President's Commission on Combating Drug Addiction and The Opioid Crisis.[7] The Commission cited Dr. Kolodny for the statement, "[t]o this day, the opioid pharmaceutical industry influences the nation's response to the crisis."

- Dr. Kolodny teaches a course at Columbia University School of Public Health that includes the role of opioid marketing in causing the opioid crisis.

- Dr. Kolodny was consulted by the United States Senate Finance Committee in 2012 and 2013 to assist the Senate in its investigation of improper marketing by opioid manufacturers, including Johnson & Johnson. Dr. Kolodny assisted the investigation by helping the Committee's lead investigator better understand the relationship between opioid manufacturers and pain organizations that promote aggressive prescribing. Dr. Kolodny also helped the investigator detect marketing bias in "educational" materials disseminated by organizations with financial ties to Johnson and Johnson.

- Dr. Kolodny served as an expert witness for the United States Senate Caucus on International Narcotics Control at a hearing on May 14, 2014. Dr. Kolodny's testimony included discussion of deceptive marketing campaign by opioid manufacturers that led to overprescribing of opioids and an epidemic of addiction and overdose deaths.

- Dr. Kolodny was consulted by the U.S. Senate Homeland Security and Governmental Affairs for an investigation of financial ties between opioid manufacturers, including Johnson & Johnson, and organizations that promote aggressive opioid prescribing.

- Dr. Kolodny served as an expert witness for U.S. Senate Homeland Security and Governmental Affairs committee on January 17, 2018. Dr. Kolodny's testimony included discussion of the deceptive marketing campaign by opioid manufacturers that led to overprescribing of opioids and an epidemic of addiction and overdose deaths.

- Dr. Kolodny served as an expert witness United States Senate Committee on Energy & Commerce, Subcommittee on Health, U.S. House of Representatives on February 28, 2018. Dr. Kolodny's testimony included discussion of the deceptive marketing campaign by opioid manufacturers that led to overprescribing of opioids and an epidemic of addiction and overdose deaths.

- Dr. Kolodny routinely assists Congressional staff of both parties on the public health consequences of opioid marketing and FDA regulation of opioid marketing.

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[6] Lin DH, Lucas E, Murimi IB, Kolodny A, Alexander GC. 2017 Mar 1. Financial Conflicts of Interest and the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain. *JAMA Intern Med.* 177(3):427-428.

[7] The President's Commission on Combating Drug Addiction and The Opioid Crisis, November 1, 2017; p. 20, n. 14.

- Dr. Kolodny's expertise is internationally recognized. The World Health Organization consults with him and invited him to lecture in Geneva, Switzerland. His talk discussed the role of opioid marketing in fueling the American opioid crisis.

- Dr. Kolodny has provided expert assistance to the National Governors Association since 2014. In 2018, he gave a presentation to a bipartisan group of governors at their summer meeting. His presentation discussed the role of marketing in fueling the opioid crisis.

- Dr. Kolodny advised the National Association of Attorneys General in their development of opioid prescribing education to correct misinformation promoted by opioid manufacturers, including Johnson & Johnson.

- Dr. Kolodny was invited to advise the National Judicial Opioid Task Force on the opioid crisis, including the role of marketing, at a meeting convened by the National Center for State Courts.

- Dr. Kolodny served as a member of the Stakeholder Review Group for the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain. The Guidelines cite Dr. Kolodny for the statement that "[a]lthough clinicians have reported favorable beliefs and attitudes about improvements in pain and quality of life attributed to opioids (*159*), **most consider prescription drug abuse to be a "moderate" or "big" problem in their community, and large proportions are "very" concerned about opioid addiction (55%) and death (48%) (*160*).**"[8] (emphasis added to show relevant citation)

- Dr. Kolodny has given keynote lectures at educational institutions across the country, including Harvard University, University of Chicago, University of Pennsylvania.

- Dr. Kolodny has been advising the State of Oklahoma in the development of opioid prescribing education that corrects opioid marketing misinformation.

Thus, contrary to Defendants' argument, Dr. Kolodny is not testifying as an expert in this case "simply because he is a doctor and, consequently, sometimes receive[d] such marketing." Mot. at 7. He is testifying as an expert witness in this case because he has more specialized knowledge about the fundamental facts of this case than any other human being on the planet, including the "marketing tactics of opioid manufacturers and their deceptive marketing and sales

[8] Footnote 160 in the CDC Guidelines is: Hwang CS, Turner LW, Kruszewski SP, Kolodny A, Alexander GC. Prescription drug abuse: a national survey of primary care physicians. *JAMA Intern Med.* 2015;175:302–4.

tactics." Mot. at 6. In fact, Dr. Kolodny testified at his deposition about many of the opioid manufacturers' deceptive promotional tactics, including:

- The use of Front Groups and Key Opinion Leaders to promote opioid friendly messaging. Exhibit 2, at 146:14-147:18; 213:15-216:16 (Kolodny Depo., Mar. 27, 2019).
- Influence on state medical boards. *Id.* at 147:13-148:15; 213:15-216:16.
- Influence on the Joint Commission and its impact on hospitals around the country. *Id.* at 148:5-149:20; 213:15-216:16.
- The "Pain is the Fifth Vital Sign" campaign. *Id.* at 113:16-114:5.
- Influence on Continuing Medical Education (CME). *Id.* at 213:15-214:16.
- Specific deceptive promotional messages used by opioid manufacturers including:
    - Opioids improve functionality;
    - Minimizing the risks and exaggerating the benefits of opioids;
    - Claiming that the risk of addiction to opioids was low. *Id.* at 117:9-133:24.

Dr. Kolodny has been researching the causes of the opioid crisis—including Defendants' deceptive marketing—since at least 2006. Exhibit 5, ¶¶ 3–4 (Declaration of Dr. Andrew Kolodny). It was in 2006 when Dr. Kolodny read an article titled: Increasing Deaths from Opioid Analgesics in the United States. *Id.*, ¶ 4. That article found that the rise in unintentional opioid deaths matched a corresponding increase in opioid sales nationwide. *Id.* Shortly thereafter, Dr. Kolodny noticed the authors of the article being attacked—in the same journal—by physicians and researchers he would later discover received funding from pharmaceutical companies. *Id.*, ¶¶ 5–7. In fact, the authors of these two papers would later be investigated by the United States Senate Finance Committee for their financial ties to opioid manufacturers. From that point forward, Dr. Kolodny continued to research, examine, and investigate the causes behind the drastic increase in opioid

prescriptions, rates of opioid addiction, and opioid-related deaths. As a result—and as shown above—Dr. Kolodny is one of the country's leading experts on the opioid crisis and its causes. Indeed, researchers, academics, legislators, clinicians, health officials, and government agencies all over the country frequently rely on Dr. Kolodny's expertise, this Court can too. *Id.*, ¶ 10.

b. Dr. Kolodny Has Personal Knowledge About Johnson & Johnson's Role In Supplying Opioids to Other Drug Manufacturers

Defendants argue that Dr. Kolodny should not be allowed to testify about J&J's role in supplying opium products into the United States because: 1) Dr. Kolodny is simply "parroting" the State's argument and 2) the testimony is irrelevant. Defendants' arguments are baseless and should be denied.

First, Defendants' argument is effectively a motion in limine, not a *Daubert* motion. Defendants are asking the Court to prevent Dr. Kolodny from testifying about facts for which he has personal knowledge. Indeed, Dr. Kolodny testified at great length about J&J's role in supplying opioid active pharmaceutical agreements to its competitors. Exhibit 2, at 204:10-208:17 (Kolodny Depo., Mar. 27, 2019). However, Defendants do not provide any basis for exclusion other than accusing Dr. Kolodny of repeating the State's narrative. Mot. at 13. But contrary to Defendants' motion, Dr. Kolodny knew about Johnson & Johnson's role in the cultivation and importation of opium from Tasmania long before this case was filed and long before he was retained by the State of Oklahoma. In March of 2015, Dr. Kolodny traveled to Tasmania to meet with Brian Hartnett, the former Managing Director of Tasmanian Alkaloids. Exhibit 5, ¶¶ 11–12 (Declaration of Dr. Andrew Kolodny). At the meeting, Mr. Hartnett explained the history of opium production in Tasmania, the history or Tasmanian Alkaloids under Johnson and Johnson's ownership, the development of the Thebaine-rich "Norman" poppy and Johnson & Johnson role in the opioid supply chain. *Id.* Thus, Dr. Kolodny is not parroting the State's case. He has personal

knowledge related to Johnson & Johnson's role in supplying opium products into the United States. Second, Defendants' argument that Johnson & Johnson's role as the primary supplier of opioids into the United States is irrelevant to this case is absurd. Indeed, when Johnson & Johnson tried to hide this information from discovery, Special Discovery Master Hetherington specifically found:

> As a former subsidiary of Johnson & Johnson, Tasmanian Alkaloids manufactured the poppy-based opiate ingredient used in many of the United States marketed and distributed opioids. The J&J Defendants had a direct financial interest in the sale of the opioid products generally, not just limited to their own branded opioids. That places J&J Defendants in a position of having a financial interest in opioids generally and possible motive relevant to issues raised in this case.

April 25, 2018 Order at 4. Johnson and Johnson's Motion is simply the latest in a string of frivolous attempts to hide its involvement in the opioid crisis from the public and should be denied.

2. Dr. Daniel Clauw

As early as 2004, Defendant Johnson & Johnson considered Dr. Daniel Clauw a Key Opinion Leader (KOL) in the field of Pain Management. He is a physician, scientist, researcher, and a patient advocate.

Medical Affairs Analgesia
MEDICAL SCIENCE LIAISON REPORT
May 2004

A. **Qualitative**

KOL	Institution	Key discussion points, comments	MSL
Clauw, D	University of Michigan, Ann Arbor, MI	Introductory meeting to provide information about the MSL program at Janssen.	Coutinho, S

Confidential **JAN-MS-00495253**

Exhibit 6 (JAN-MS-00495253 - excerpt).

At that time, Johnson & Johnson considered Dr. Clauw skilled, experienced, well-respected, and credible enough to help J&J market its drugs and influence doctors in the field of pain management.[9] However, faced with an impending trial involving various marketing tactics—including the use of KOLs— Johnson & Johnson now takes the position that, Dr. Clauw does **not** have the "knowledge, skill, experience, training [and] education" to testify in this case. Mot. at 4. Defendants' motion is meritless and should be denied.

Dr. Clauw has been a thought leader in the field of pain management for over 25 years. Currently, Dr. Clauw is a Professor of Medicine, Division of Rheumatology, a Professor of Psychiatry, and a Professor of Anesthesiology at the University of Michigan. He also serves as Director of the Chronic Pain and Fatigue Research Center, a comprehensive multidisciplinary center where internationally-renowned clinicians and investigators conduct research on the mechanisms and most effective treatments of conditions that have chronic pain and fatigue as core symptoms.

Defendants argue that Dr. Clauw should not be allowed to testify about their marketing because Dr. Clauw lacks a formal marketing degree and is not a trained statistician. However, a marketing degree is not required—nor is a statistical analysis. Indeed, the *Pfizer* case cited by Defendants explicitly recognizes that "the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience." *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 461 F. Supp. 2d 271, 277 (D.N.J. 2006). Dr. Clauw has dedicated almost his entire career to treating, studying, researching, and teaching in the field of pain management. As a result, he has witnessed—and spoken out against—Defendants' improper promotion of opioids his entire career.

[9] Despite their invitations, Dr. Clauw never accepted money from or spoke on behalf of the Defendants in this case.

Defendants further argue that because Dr. Clauw was not visited by opioid sales representatives he lacks the necessary qualifications to opine about the influence of pharmaceutical marketing on opioid prescribing. Mot. at 5. However, sales reps were only one aspect of Defendants' pervasive marketing efforts. Dr. Clauw personally experienced many of the other ways in which Defendants influenced doctors across the country including for example studies, publications, conventions, conferences, etc. Indeed, Dr. Clauw testified that as a thought leader, he frequently presented at the very meetings and conferences where Defendants marketed their drugs to doctors from all over the country:

> So it's well-known and well understood that a lot of the money that is generated in a scientific meeting comes from the companies that are, if you will, sponsoring the meeting. And in the – starting in the mid -- the late 1990s and -- and going through the 2000s, you would just see a lot more of the opioid manufacturers at these meetings with the really big exhibits, giving out material to physicians that came to those meetings, purporting the benefits of opioids and minimizing the risks. So these were meetings, everything from meetings that I would attend annually like the American Pain Society meeting or meetings that I might attend intermittently that I'd be asked to give a talk at. But there was a -- really sort of a proliferation of -- of marketing -- very obvious marketing along these lines by a number of the opioid manufacturers in this time frame.

Exhibit 7, at 168:6-23 (Clauw Depo., Mar. 26, 2019).

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> So a big part of my life is to go and give talks at meetings. And at almost all scientific meetings, there will be exhibits. And so I have seen over the course of -- you know, this week, I'm, you know, going to two different scientific meetings later to give talks, and there will be exhibits from the -- the pharmaceutical manufacturers, the device manufacturers. And so I can't remember all the different meetings. If you looked at my CV, you'd see that I give a lot of talks. And in a lot of those settings, if they -- and all have been sponsored by industry, you -- you would see a lot of opioid marketing material and things like that at those meetings. And, again, my view is that that did play a big role in influencing prescribing.

Id. at 173:15-174:4.

Thus, Defendants' argument that "Dr. Clauw admits he has no recent personal experience with pharmaceutical companies' marketing of opioids and its influence on his or other doctors' prescribing practices" is wrong. Mot. at 5. Indeed, *because* Dr. Clauw experienced how Defendants used speakers to influence others, he felt compelled to counter their message where he could:

> The reason that pharmaceutical companies want people like me to do work for them in any way possible is they -- you know, that they call us key opinion leaders, is that we can in -- we can, and do, influence opinions, and I -- I view that as an incredible responsibility to chronic pain patients that's sort of been bestowed upon me. And so I spend a lot of time giving free talks to patient groups and things like that and -- and doing advocacy work and things like that, because I think it's part of my responsibility as a thought leader in the field of pain.

Exhibit 7, at 239:8-19.

Defendants also complain that Dr. Clauw should not be able to testify that in his experience, most doctors do not read drug labels. Mot. at 10. Defendants again ignore Dr. Clauw's extensive experience as a thought leader in the field of pain management. Unlike the cases cited by Defendants, Dr. Clauw is not testifying about the potential impact of any label changes or the general understanding of all physicians. Mot. at 10-11. As Dr. Clauw made clear in his testimony, he is opining based on his professional experience as a thought leader in the field for over 30 years.

> Q. How do you know that the average U.S. physician doesn't also read labels before prescribing drugs with serious risks, like opioids?
>
> A. Well, because I've talked to a lot of physicians over the course of my career and given a tremendous number of lectures to physicians about therapies and things like that. That isn't how they get their information.

Exhibit 7, at 45:6-13.

Dr. Clauw went on to testify that in his experience, doctors get their information from a variety of sources. *Id.* at 47:2-11. Defendants cannot simply ignore Dr. Clauw's extensive

professional experience to argue that he is not qualified to testify. Dr. Clauw has been an expert in the field for decades. He is qualified to testify in this case.

D. The Challenged Experts' Opinions Are Relevant And Reliable.

The challenged opinions are relevant, reliable, and will assist the trier of fact. "Expert witnesses may take known facts, together with experience and knowledge of causation factors, and draw a rational conclusion." *Orth v. Emerson Elec. Co., White-Rodgers Div.*, 980 F.2d 632, 637 (10th Cir. 1992). Expert testimony assists the trier of fact when it provides information beyond the common knowledge of the trier of fact. *Daubert*, 509 U.S. at 591.

Defendants' efforts to discredit the experts' causation testimony misapprehend both the relevant causation law and the Rules of Evidence. In the case of an indivisible public nuisance injury, the plaintiff must simply show that a "defendant's act was a *contributing* (not *substantial)* factor in producing the plaintiff's injuries." *Lee v. Volkswagen of Am., Inc.*, 1984 OK 48, ¶ 29, 688 P.2d 1283, 1289 (emphasis in original). And, an expert's opinion on causation need not prove causation by itself. *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 564-65 (11th Cir. 1998) ("The expert's testimony does not have to prove the case by itself—it must merely constitute one piece of the puzzle that the party is attempting to assemble before the jury.").

J&J attempts to impose a test for expert opinion reliability that does not exist. "Where the expert states the reasons for his opinions and conclusions, they are not *ipse dixit*." *Covel v. Rodriguez*, 2012 OK 5, ¶ 15, 272 P.3d 705, 712. Further, experts can base their testimony on "professional studies or personal experience." *Christian v. Gray*, 2003 OK 10, ¶ 13 (citing *Kumho*, 526 U.S. at 153, 119 S.Ct. at 1176). Here, the State's experts base their opinions regarding Defendants' marketing on both. They do not have to conduct regression analyses, individually

survey doctors, or address all other potential causal factors in order to opine on the effect of pharmaceutical marketing as J&J would have the Court believe.

Indeed, courts have specifically eschewed these restrictions. In *Smith v. Pfizer, Inc.*, plaintiff sued Pfizer over its marketing of Neurontin to treat chronic pain. 714 F. Supp. 2d 845, 848 (M.D. Tenn. 2010). Plaintiff offered an expert to testify on the effects of the defendants' marketing based on a review of "defendants' internal documents, government records, sales and industry data, and scholarly studies." *Id.* at 855. Defendants moved to exclude the expert, arguing that he "reaches his conclusions by mere *ipse dixit* and that he employs no ascertainable methodology at all." *Id.* at 856. In denying the defendants' motion to exclude the testimony, the court held that the expert's conclusions were reliable "despite the fact that he did not interview individual doctors to determine why they personally prescribed Neurontin." *Id.* Likewise, the court dismissed the defendants' argument that an expert must consider other explanations for the increase in prescriptions. *Id.* at 857 ("The defendants can address the relative magnitude of other potential factors on cross examination."). As was the case in *Smith*, J&J's alleged deficiencies go to weight, not admissibility, and are more properly the subject of cross-examination at trial.

Likewise, Defendants' attacks on the sources of the facts underlying the experts' opinions are not a proper inquiry for a motion to exclude. "The factual basis of an expert's testimony generally goes to the credibility of the testimony and the party opposing can attack the factual basis on cross-examination." *Covel v. Rodriguez*, 2012 OK 5, ¶ 15, 272 P.3d 705, 712; *Black v. Ferrellgas, Inc.*, 2018 OK CIV APP 38, ¶ 21, 417 P.3d 1267, 1273 ("The trial court's gatekeeping role is designed to test the expert or scientific means by which the expert arrives at a conclusion, not a test of the underlying facts upon which the expert relies."). Indeed, an expert may base her

opinion on facts or data that the expert has been made aware of or personally observed, and the facts or data need not be admissible. 12 O.S. § 2703.

The State's experts rely on proper facts and data, analyze those facts and data through the lens of their extensive knowledge and experience regarding the causes and effects of the opioid crisis, and draw rational conclusions. Their testimony is therefore relevant and reliable.

1. Dr. Andrew Kolodny

As discussed above, Dr. Andrew Kolodny's opinions in this case are based on his extensive personal and professional experience, skill, knowledge, and education gained from researching opioid manufacturers' role in creating the opioid crisis. Dr. Kolodny himself has published articles regarding the causes and effects of the opioid crisis. *See, e.g., supra* fn. 4. In addition, the basis for the facts and opinions upon which Dr. Kolodny will testify include his review of the relevant medical literature, public documents, the documents produced by the parties in this case, and the deposition testimony provided in this case. Indeed, Dr. Kolodny has undertaken an extensive review of the documents produced in this case. At his deposition, Dr. Kolodny brought several boxes, with tabbed binders, of Defendants' documents he referred to throughout his testimony.

For example, Dr. Kolodny reviewed sales representative call notes for each Defendant and confirmed that the misleading and deceptive messages he was aware were being disseminated on a national scale were also being spread here in Oklahoma. They were. Dr. Kolodny also reviewed opioid prescription sales data and trends in Oklahoma to confirm prescriptions increased dramatically in Oklahoma like in the rest of the country. They did. Likewise, Dr. Kolodny reviewed incidences of unintentional poising and deaths related to opioid overdoses to confirm those increased here—in lockstep with increasing prescriptions—like in the rest of the country. They did.

Further, Dr. Kolodny has published articles and conducted studies on the very issues that J&J seeks to prevent him from testifying on. For example:

> Q: Have you ever done a study to measure the impact of pharmaceutical sales in a marketing campaign?
>
> ****
>
> A: I don't think I've conducted my own study. I have published on this subject. I have studied this subject, and I am very familiar with studies of this subject and have worked with these authors who have done some of these studies. Studies, for example, that have shown that in counties in the United States, including Oklahoma, where doctors were paid more by drug companies, mostly dinners, where doctors took more money from drug companies, more opioids were prescribed. And another more recent study that was published just a few months ago that showed that where doctors took the most money from drug companies in those counties, more people were dying of prescription opioid overdoses than in counties where doctors took less money from drug companies. So I have not conducted my own unique study, but I have studied this topic extensively, and I've written on this topic. So I do feel that I'm an expert on this subject.

Exhibit 2, at 84:10-12, 85:4-24.

> Q: Are you an epidemiologist?
>
> A: I teach epidemiology. I teach at the Mailman School of Public Health, and I do research in epidemiology. I'm not sure that there is a formal degree in epidemiology, but I certainly have expertise in the epidemiology of opioid addiction in the United States.
>
> Q: What was the last epidemiology study that you designed?
>
> A: There's a study I've designed that I'm working on right now with a student at Columbia University. This is a study on the epidemiology of opioid addiction in the United States. What we're doing is we're analyzing data, treatment episode data that comes from the federal government for people receiving treatment for opioid addiction.
>
> We're also analyzing data on opioid overdose mortality, and we're analyzing data from. HCUP, which is a federal agency, data on hospitalizations involving opioid overuse.

Id. at 87:10-88:2.

Thus, unlike the rheumatologist in the *Pfizer* case cited by defendants, Dr. Kolodny's opinions are based on much more than the typical physician's experience. Mot. at 9, 13. In *Pfizer*, the Court excluded as unreliable the rheumatologist's expert opinion that Defendants' prescriptions were heavily influenced by advertising and promotion because that opinion was "based primarily on his personal experiences with [Defendant's] marketing representatives and patients who requested [Defendant's] prescriptions, as well as 'common sense,' and informal discussions with other doctors." *Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 461 F. Supp. 2d 271, 277 (D.N.J. 2006). But the *Pfizer* court went on to clarify that "this is not to say that 'the personal experience or knowledge of the expert alone is not to be trusted. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience.'" *Id.* citing *United States v. Frazier*, 387 F.3d 1244, 1296 (11th Cir. 2004); *see also Kumho*, 526 U.S. at 150; *Maiz v. Virani*, 253 F.3d 641, 668-69 (11th Cir. 2001) ("[T]here is no question that an expert may still properly base his testimony on 'professional study or personal experience.'")

Thus, Dr. Kolodny's opinions are firmly reliable and should not be excluded.

2. Dr. Daniel Clauw

For the same reasons discussed above with respect to Dr. Kolodny, Dr. Clauw's opinions are reliable and should not be excluded. Dr. Clauw's opinions are based on over 25 years of experience as a physician, a scientist, a researcher, and a patient advocate in the area of pain management. And like Dr. Kolodny, the basis for the facts and opinions upon which Dr. Clauw will testify include his review of the relevant medical literature, public documents, the documents produced by the parties in this case, and the deposition testimony provided in this case. Dr. Clauw has long been recognized as a thought leader in the field of pain management and lectures to

doctors all over the world. He testified that he personally experienced many of the ways in which Defendants influenced doctors across the country including studies, publications, conventions, and conferences. Indeed, Dr. Clauw testified that as a thought leader, he frequently presented at the very meetings and conferences and witnessed Defendants marketing their drugs to doctors from all over the country.

> Q: How do you know that any of those doctors were influenced, let alone improperly influenced, in their prescribing decisions by Defendants' improper and aggressive marketing of their opioid products?
>
> A: I saw this firsthand myself. I -- you know, I would -- I would go to national scientific meetings and see that the -- you know, that the -- the opioid manufacturers were flooding the national scientific meetings and -- and, you know, basically, you know, giving out promotional material that misstated the effectiveness of opioids and -- and underplayed by a significant extent the safety issues associated with opioids. And so I -- can I say which of those practices by which of the opioid manufacturers led to that increase? No. That's not really my area of expertise. But there was a very clear, very dramatic change in opioid prescribing, and that was the major force that was driving it, were the -- again, the opioid manufacturers, not just putting out material themselves, but influencing professional societies and lobbying and creating new nonprofit organizations that they almost entirely funded that put out material that looked like it wasn't coming from the opioid manufacturers but, in fact, it was.

Exhibit 7, at 164:11-165:10

And like Dr. Kolodny, Dr. Clauw also reviewed the relevant Oklahoma materials and data to confirm that the same deceptive messaging and increase in opioid prescriptions he witnessed at a national level occurred here in the State of Oklahoma as well. Thus, for these reasons, Dr. Clauw's testimony is reliable and should not be excluded.

3. Dr. William B. McCallister

The Teva Defendants seek to exclude Dr. McAllister's testimony on the grounds that it is not relevant to the issues in this case. Motion at 5-10. In doing so, the Teva Defendants take the position that history is irrelevant, teaches us nothing, and that everything that happens outside of

Oklahoma is irrelevant. However, one cannot view the current crisis in Oklahoma in a vacuum separated from the history of opioid use globally and in the United States. Doing so would ignore what we all learned in school—history does matter. As set forth above, the Court should only decide the admissibility of Dr. McAllister's testimony upon a full record. *See supra* Section A. Regardless, the Teva Defendants are incorrect. Dr. McAllister's testimony is relevant and helpful for the trier of fact to understand what Defendants knew or should have known about opioids, their addictive potential, and the consequences of attempting to increase opioid use on a massive scale.

Dr. McAllister is the preeminent historian on the international drug control regime, and a leading expert on domestic narcotic drug policy, having dedicated his career to studying the history of narcotics crises and their regulatory and diplomatic solutions. In fact, Dr. McAllister has "conducted research in primary and secondary sources that no one else has done" and has "a body of knowledge which is unique." Exhibit 8, at 29:16-30:01 (McAllister Depo., Mar. 19, 2019). Dr. McAllister currently serves as the Chief of the Special Projects Division of the State Department Office of the Historian, and also holds the position of Adjunct Associate Professor in the Graduate School of Foreign Service at Georgetown University. His areas of expertise include diplomatic history, U.S. history, World history, and U.S. foreign policy, with particular expertise in foreign and domestic policies related to controlled substances. Previously he was the Acting General Editor of the "Foreign Relations of the United States" series, in the Office of the Historian, U.S. Department of State; was a Research Historian in the Office of the Historian, U.S. Department of State; was a Faculty Consultant for the Teaching Resource Center and Assistant Professor in the Department of History at the University of Virginia; and a Lecturer in History at the University of Virginia.

Dr. McAllister intends to testify regarding: (1) the historical relationship between human beings and opiates; (2) the impact of the Asian opium trade and the international response thereto; (3) the history of the interrelationship between opiate addiction and opiate-related epidemics in foreign countries to those phenomena in the United States; and (4) efforts to abate previous opiate addiction epidemics and to prevent subsequent addiction epidemics. Dr. McAllister further concludes that his study of the past international opium addiction crises imparts three lessons: (a) "due to the voracious appetite these drugs create, the sale of opioid products is a highly profitable endeavor"; (b) "when a human populace is over-supplied with opioids, an addiction crisis will likely ensue"; and (c) "when such a crisis arises, it can be brought under control and abated through educational, regulatory, and treatment efforts." McAllister Disclosure at Part B. These issues are relevant and will assist the trier of fact for several reasons.

First, Defendants' knew or should have known that opioids were addictive and that a dramatic increase in their use (as Defendants intended) would lead to an addiction crisis. The Teva Defendants ultimately refer to this in their Motion to Exclude as the "foreseeability" of the current opioid epidemic in Oklahoma. Motion at 16. It is hard to fathom how the foreseeability of this crisis is not relevant to Defendants' creation of it. Defendants specifically identified all of the areas they needed to target and influence to promote the broadest availability and use of opioids possible. *See, e.g.*, Exhibit 9 (excerpt from JAN-MS- 00330384); Exhibit 10 (excerpt from TEVA_OK_00044404). Such plans could only be developed by Defendants in the context of their historical observations of the key stakeholders they would need to influence. Moreover, the very first paragraph of the State's Petition refers to the historical use of opioids and its significance to the context of this case. Any question as to the relevance of historical opioid crises (including the

United States' own history of opioid crises) and the insight they provide into the current crisis would go to the weight, not admissibility of such an opinion.

Second, what Defendants knew or should have known about the addictive power of opioid drugs based on history is also relevant to falsity of many of the representations they made in their marketing efforts. For example, if Defendants knew that opioids are highly addictive—which they did—then it would be misleading to say otherwise in marketing efforts. The history of opioids and their use is therefore helpful for the trier of fact to weigh Defendants' statements regarding opioids' safety and efficacy. In fact, Defendants' own marketing materials talk about the history of opioid use. *See, e.g.*, Exhibit 11 (JAN-MS-03090610); Exhibit 12 (TEVA_OK_05547098). Thus, Dr. McAllister's testimony about the history of opioid drugs, regulation and crises is relevant to the manner in which Defendants' caused the current opioid crisis.

Third, Dr. McAllister's testimony is relevant to the question of abatement of the public nuisance. Dr. McAllister's testimony specifically goes to show that history has several examples of how temporary public health crises related to opioids can be abated. Thus, Dr. McAllister's testimony is further admissible on this basis.

CONCLUSION

For the reasons set forth above, the State respectfully requests the Court deny Defendants' Motions to Exclude in their entirety, and for such further relief the Court deems proper.

Respectfully submitted,

Michael Burrage, OBA No. 1350
Reggie Whitten, OBA No. 9576
WHITTEN BURRAGE
512 N. Broadway Avenue, Suite 300
Oklahoma City, OK 73102
Telephone: (405) 516-7800

Facsimile: (405) 516-7859
Emails: mburrage@whittenburragelaw.com
rwhitten@whittenburragelaw.com

Mike Hunter, OBA No. 4503
ATTORNEY GENERAL FOR
THE STATE OF OKLAHOMA
Abby Dillsaver, OBA No. 20675
GENERAL COUNSEL TO
THE ATTORNEY GENERAL
Ethan A. Shaner, OBA No. 30916
DEPUTY GENERAL COUNSEL
313 N.E. 21st Street
Oklahoma City, OK 73105
Telephone: (405) 521-3921
Facsimile: (405) 521-6246
Emails: abby.dillsaver@oag.ok.gov

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above and foregoing was emailed on April 23, 2019, to:

Sanford C. Coats
Joshua D. Burns
CROWE & DUNLEVY, P.C.
Braniff Building
324 N. Robinson Ave., Ste. 100
Oklahoma City, OK 73102

Sheila Birnbaum
Mark S. Cheffo
Hayden A. Coleman
Paul A. Lafata
Jonathan S. Tam
Lindsay N. Zanello
Bert L. Wolff
Marina L. Schwartz
Dechert, LLP
Three Byant Park
1095 Avenue of Americas
New York, NY 10036-6797

Patrick J. Fitzgerald
R. Ryan Stoll
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
155 North Wacker Drive, Suite 2700
Chicago, Illinois 60606

Robert G. McCampbell
Nicholas Merkley
GABLEGOTWALS
One Leadership Square, 15th Floor
211 North Robinson
Oklahoma City, OK 73102-7255

Steven A. Reed
Harvey Bartle IV

Brian M. Ercole
MORGAN, LEWIS & BOCKIUS LLP

Jeremy A. Menkowitz
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921

Benjamin H. Odom
John H. Sparks
Michael Ridgeway
David L. Kinney
ODOM, SPARKS & JONES PLLC
HiPoint Office Building
2500 McGee Drive Ste. 140
Oklahoma City, OK 73072

Stephen D. Brody
David Roberts
O'MELVENY & MYERS LLP
1625 Eye Street NW
Washington, DC 20006

Daniel J. Franklin
Ross Galin
O'Melveny & Myers LLP
7 Time Square
New York, NY 10036
Telephone: (212) 326-2000

Robert S. Hoff
Wiggin & Dana, LLP
265 Church Street
New Haven, CT 06510

Britta Erin Stanton
John D. Volney
John Thomas Cox III
Eric Wolf Pinker
LYNN PINKER COX & HURST LLP 2100
Ross Avenue, Suite 2700 Dallas, TX 75201

200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131

Charles C. Lifland
Jennifer D. Cardelus
Wallace Moore Allan
O'MELVENY & MYERS LLP
400 S. Hope Street
Los Angeles, CA 90071

Larry D. Ottaway
Amy Sherry Fischer
FOLIART, HUFF, OTTAWAY & BOTTOM
201 Robert S. Kerr Ave, 12th Floor
Oklahoma City, OK 73102

Eric W. Snapp
Dechert, LLP
Suite 3400
35 West Wacker Drive
Chicago, IL 60601

Benjamin Franklin McAnaney
DECHERT LLP
2929 Arch Street
Philadelphia, PA 19104

Amy Riley Lucas
O'MELVENY & MYERS LLP
1999 Avenue of the Stars, 8th Floor
Los Angeles, California 90067

Michael Burrage